

C-CFR Data Sharing Policy

Since the establishment of the Colon Cancer Family Registry (C-CFR) in 1996, there has been a clear vision of how its resources are to be shared with scientists and clinicians who seek to collaborate with the C-CFR in interdisciplinary colorectal cancer research. The C-CFR is committed to sharing data and biospecimens widely and in a timely manner. This is achieved through a staged data sharing plan. As the overall C-CFR database is composed by an ever increasing number of relational modules, these different stages are made operational as soon as the data are ready for each level. Biospecimens are also shared according to their availability through the Level 3 process described below. This policy has been adapted through the years to meet new NIH and NCI requirements and will continue to be responsive to published NCI guidelines.

Level 1

At this level, sharing is achieved through an informative and comprehensive public website with periodically updated summary data showing the status of the resource.¹ In addition, tables showing the timeline for release of new molecular and epidemiologic data are posted on the website.²

Knowledgeable staff are also on hand for direct and immediate communication with prospective applicants, including program and contract staff.

Level 2

This level of sharing is achieved through a Summary Data Access System (SDAS) which will allow direct queries from the investigators using the resource and will be web-accessible through the CFR NCI website. SDAS will include pre-built summary data tables for important variables as well as a Query builder interface that enables the construction of *ad hoc* summary data tables. The anticipated date for public release (web-based access) is March 2007.

Genotyping and other molecular data will be made accessible according to NIH stated policies.

Level 3

A unique system of scientific review has been created so that investigators worldwide may propose and lead research projects that include C-CFR data and biological material, in collaboration with relevant C-CFR sites. A flow chart outlining the process is attached. A major supporting tool for this level of data sharing is the Research Application Database (RAD). Its major

functions include a searchable database of research applications and publications, and a workflow tracking system for the entire application and review process. Key features include the capability to search application documents for specific fields and keywords; web-based application and review forms; workflow scheduling with reminders and work lists; access to summary statistics of active C-CFR projects; and access to publication information.

With this review process in place, proposals for collaborative projects are evaluated fairly and carefully, and in consideration of scientific merit, overlap with studies in progress, impact on the inventory of biological material and protecting participant confidentiality. The application and review process is clearly defined at each step, and expert guidance and feedback is provided during each phase, from idea to implementation (Appendix 1).

The year-round participation of an accomplished panel of independent scientific reviewers, the C-CFR Advisory Committee, safeguards against an activities that may be perceived as conflicts of interest or breaches of confidentiality.

Research is facilitated through investigator access to a central informatics database. Initially, investigators may obtain summary data to develop a proposal. After projects have been completed, investigators are expected to submit their published CFR-study results back into the central database. In this way, C-CFR resources accessible to the scientific community at large are simultaneously accessed and expanded. Finally, cleaned molecular data sets are released to the public 6 months after publication of the initial manuscript.

These guidelines and processes are subject to change to reflect future NCI policies concerning data and biospecimen sharing.

¹Already operational.

²This will happen as of the end of November.